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Applicants : Thomas Hille and Lothar Deurer
Serial No. : 09/486,266 Confirmation No.: 3529
Filing Date : May 3, 2000

REMARKS

In the Office Action mailed April 23, 2002, the Examiner acknowledged amendment C and drawings corrections. The Examiner has rejected claims 22-33, 35-39, 41-49, 53-55 and 57-66 under 35 U.S.C. 103(a) as being unpatentable over either US Patent No. 4,390,520, or U.S. Patent No. 5,225,199, each by itself or in combination. The Examiner states that applicant's arguments filed February 12, 2002 are not persuasive. To unambiguously distinguish the present invention from prior art such that its inventiveness becomes apparent, applicant herein amends claim 22, combining the subject matters of claims 22 and 58, deletes claim 58, and amends claim 65, which depended from claim 58, to depend from claim 22 and to remove films from its subject matter. Applicant respectfully traverses this rejection.

Applicant states that '520 teaches an antiphlogistic analgesic adhesive which comprises a flexible substrate. Said substrate preferably has a property of expanding in at least one direction to prevent a disagreeable sense of tension (col. 2, last line, to col. 3, line 2). '199 teaches a plaster comprising a film layer which possesses 30% to 150% elongations, respectively, in the two directions intersecting at right angles, and 1.0 to 5.0 ratio between the two directions intersecting at right angles. '199 further discloses that it is important to reduce the physical stimulation caused by plaster preparations in order to reduce skin rash (col. 4, lines 11-13). The plasters are required to follow the expansion and contraction of the skins in body action to some extent (col. 4, lines 17-20). In addition, films of over 5.0 ratio, namely of extremely low elongation in one direction, " ...

cannot follow the expansion and concentration of the skin satisfactorily to cause several problems or troubles, for example, making the application feeling unpleasant because of skin stretched, ... thus being concluded to be unsuitable" (col. 4, lines 55-61). Thus, it has to be emphasized that '199 considers a backing being expandable in only one direction as unsuitable to solve the problem of the present invention. That is, '199 teaches that the substrate of a plaster **has to be expandable in both directions** (longitudinal and transversal) in order to minimize physical stimulation of skin and that a substrate being expandable in only one direction is unsuitable to provide a plaster which cause no skin rash and resists peeling. Thus, the teaching of '199 is directly opposed to that contemplated in the present invention.

Further, '199 states that not only is a film which is expandable in two directions required to provide a plaster which causes no skin rash and resists peeling, but also an ultra thin film is desired (col. 5, lines 41-65, in particular, lines 60-65). Such a film might be the uppermost layer of a patch applied to the patient's skin or being further covers by a backing sheet. Such a backing sheet might be a fabric or paper-like substances. The expanding properties of the backing layer are not specified by '199 and it should be noted that the backing layer is always present in addition to the expandable film. '199 does not provide any hint that a woven or non-woven fabric might suitably replace the ultra-thin and expandable film.

Applicant would like to draw the Examiner's attention to the examples of the present application. In particular, the results obtained by the plaster according to comparison example 1 (bidirectionally elastic woven polyester fabric as backing layer) demonstrate an approximately equal wearing comfort compared to a plaster comprising the unidirectionally elastic backing layer of the present invention. This result is surprisingly and could not have been anticipated from the teachings of the '199 reference.

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In combination with the disclosure of '520, it is reasonable to expect that the skilled artisan

would provide a pharmaceutical plaster according to '520 with a film having an elongation of 30% to 150% expandable in two directions intersecting at right angles rather than choosing a unidirectional elastic material. A plaster comprising a unidirectionally elastic backing layer is definitely not suggested by the combined view of the disclosures of '520 and '199.

Beyond the approximately equal wearing comfort, the plaster of the present invention is advantageous over plasters comprising bidirectionally elastic backing layers in that the process of its production is less vulnerable to complications predominantly due to an undesired curling effect. Thus, the production of the inventive plasters is more reliable and thus less costly compared to plasters comprising bidirectionally elastic backing layers. Cited references do not indicate that a fabric being elastic in one direction only can solve the problems underlying the present invention by providing a transdermal therapeutic system avoiding the sensation of a foreign body on the skin. Therefore, we believe that the subject matter of amended claim 22 was not made obvious by the combined view of cited references.

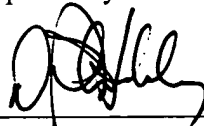
It is respectfully submitted that the application is now in condition for allowance, and such action is requested. No new matter has been added. The examiner is invited to telephone the undersigned if there are any matters which could be discussed to expedite the prosecution of the above-identified application.

Date:

August 23, 2002

DPH/KRV
Attached: Marked Up Claims
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Respectfully submitted,



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Addendum

Attachment 1

TRANSDERMAL THERAPEUTIC SYSTEM COMPRISING A RESERVOIR-T
PRESSURE-SENSITIVE ADHESIVE LAYER AND A BACK LAYER WITH
UNI-DIRECTIONAL RESILIENCE

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